Remarks

Following entry of the foregoing amendment, claims 1-24 are pending.

Amendments

Claims 25-40 were canceled without prejudice as being drawn to non-elected inventions.

Rejection Under 35 U.S.C. § 103

Claims 1-24 were rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,797,898 to Santini et al. (hereinafter "Santini") in view of U.S. Patent No. 6,071,819 to Tai et al. (hereinafter "Tai"). The rejection is respectfully traversed.

The Patent Office has the burden under 35 U.S.C. § 103 to establish a *prima facie* case of obviousness. *See* In re Fine, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). "It can satisfy this burden only by showing some *objective teaching* in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references." Id. As explained below, no *prima facie* case of obviousness has been established in the present application.

There Is No Motivation to Combine Santini with Tai

"Determination of obviousness can not be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention." ATD Corp. V. Lydall, Inc., 159 F.3d 534, 546 (Fed. Cir. 1998). It is respectfully submitted that only in hindsight of Applicants' disclosure would one of ordinary skill in the art have been led to combine and extend the disclosures of Santini and Tai to somehow derive the presently claimed device arrays.

The CAFC has warned that "the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for showing of the teaching or motivation to combine prior art references." In re Dembiczak, 175 F.3d 994 at 999 (Fed. Cir. 1999). While the suggestion to combine may be found in explicit or implicit teachings within the references, from the ordinary knowledge of those skilled in the art, or from the nature of the problem to be solved, the "question is whether there is something in the prior art *as a whole* to suggest the desirability of making the combination. WMS Gaming, Inc. v. International Game Technology, 184 F.3d 1339 at 1355 (Fed. Cir. 1999). "The range of sources available, however, does not diminish the requirement for *actual evidence*. That is, the showing must be *clear and particular*." In re Dembiczak, 175 F.3d 994 at 999 (Fed. Cir. 1999) (emphasis added). The Office Action lacks such evidence of a clear and particular motivation. Instead, the Office Action's rationale is *conclusory*, indicating that it would be obvious to combine the art to achieve the benefits taught and claimed by the Applicants.

The Office Action Evidences Improper Hindsight Reconstruction

One of ordinary skill in the art would not have been led to combine Santini with Tai to derive Applicants' claimed devices, absent improper hindsight reconstruction based on Applicants' disclosure, because nothing in Santini suggests a problem to be solved that would lead one of ordinary skill in the art to search for or identify Tai. That in hindsight of Applicants' disclosure a skilled artisan arguably may be able to recognize, cull, modify, and combine certain claim elements from disparate references is not evidence of a clear and particular motivation to combine those references. *See, e.g.*, In re Lee, 61 U.S.P.Q.2d 1430, 1433-34 (Fed. Cir. 2002). The Court of Appeals for the Federal Circuit has explained that to sustain an obviousness

rejection "particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed." In re Kotzab, 217 F.3d 1365, 1371 (Fed. Cir. 2000) (emphasis added). Here, it appears that the Examiner worked backwards from Applicants' flexibly-connected, multi-component array solution, and apparently overlooked alternative approaches that one of ordinary skill in the art might reasonably have taken toward solving the tissue conformance problem—alternative approaches that might *not* have entailed the use of *multiple* rigid devices—*had one of ordinary skill in the art worked with no knowledge of the claimed invention.* For example, one might have tried to select a substrate material that was a thermoplastic elastomer or another flexible material in a *single* large microchip device, and not an array of smaller ones flexibly connected.

The Combination of Tai with Santini Would Not Be Operable

Furthermore, one of ordinary skill in the art working from Santini would have been unmotivated to use the teachings of Tai because the combination would be unworkable with the devices and applications of Santini. Tai, which is directed to shear stress sensors for *aeronautical* applications, is not remotely directed to or concerned with *biomedical* applications, as is Santini. Moreover, Tai does not teach anything about storing, releasing, or selectively exposing sensitive molecules and materials. These differences underlie the reasons why one skilled in the art would not have been motivated to combine the teachings of Tai and Santini.

Tai's devices and methods require layers of flexible polyimide integrated within the microchip devices. Fabrication of polyimide layers entails a *high temperature* curing process (e.g., greater than 100 °C), and the processes for making Tai's devices include building the

flexible polyimide connecting material into the microchip structure, as an *integral* part of the structure. Tai's sensor devices have flexible polyimide layers built into both sides of the microchip devices; the microchip devices are not built separately and then connected together in a later step. Therefore, the Tai fabrication process necessarily requires the microchip devices, *and any reservoir contents in the devices*, to be exposed to the high temperatures for curing the polyimide.[1] This would be highly undesirable to one skilled in the art working from Santini, because the high processing temperatures generally would not work with the reservoir contents of the Santini devices. Most, if not all, of the chemical reservoir contents of Santini's devices would be destroyed or substantially deactivated by exposure to the polyimide curing temperatures taught by Tai, thereby rendering the device substantially inoperable. For example, a protein drug or enzyme-based sensor would be destroyed at temperatures even approaching 100 °C for more than a few seconds (e.g., as would typically be expected when curing a polyimide).

In addition, Tai teaches that the polyimide layers are on *both* sides of the microchip device. Thus, with the microchip device covered by a polyimide layer, the microchip devices could not expose or release reservoir contents therefrom—without making substantial modifications. Accordingly, the artisan of ordinary skill would <u>not</u> find the teachings of Tai to

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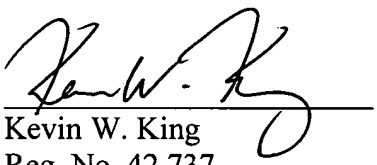
[1] While Applicants disclose (1) the means for flexibly connecting microchip device elements may include a "flexible supporting layer attached to a surface of the device elements" and (2) the supporting layer can comprise a polyimide, Applicants' devices would be made and attached to a polyimide supporting layer *without* exposing reservoir contents to high temperature processing conditions for extended periods. For instance, the flexible layer can be made separately and then the microchip device elements surface mounted (e.g., with an adhesive) or mechanically attached. See p. 8, lines 26-31.

be a desirable, readily adaptable, technique for making the devices of Santini fit to a curved surface, particularly a curved tissue surface for drug delivery or chemical biosensing.

For the foregoing reasons, it is submitted that no *prima facie* case of obviousness has been established for Applicants' claims in view of the prior art as a whole. Applicants therefore respectfully request that each of claims 1-24 be allowed.

Respectfully submitted,



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